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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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EXAMINER

CHANNAVAJJALA, LAKSHMI SARADA

| ART UNIT | PAPER NUMBER |
|----------|--------------|
| 1615 | J |

DATE MAILED: 05/21/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|--------------------------------------|------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 10/074,847 | ARMONTI ET AL. |
| | Examiner Lakshmi S. Channavajjala | Art Unit 1615 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on ____ .
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) Claim(s) ____ is/are allowed.
- 6) Claim(s) 1-19 is/are rejected.
- 7) Claim(s) ____ is/are objected to.
- 8) Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on ____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on ____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. ____ .
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2 . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt of Information Disclosure statement, preliminary amendment A and preliminary amendment B, all dated 2-13-02 is acknowledged.

Claim Objections

Claim 7 is objected to because of the following informalities:

Claim 7 recites, “selected in the group comprising” which is improper. The proper claim language should be “selected from the group consisting of”.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

1. Claim 6 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Instant claim requires “oligoelements” along with dermoprotective vitamins and antioxidants in the composition. However, applicants have not described or defined what “oligoelements” are.

The factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is “undue” are:

- (A) The breadth of the claims;
- (B) The nature of the invention;
- (C) The state of the prior art;

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- (D) The level of one of ordinary skill;
- (E) The level of predictability in the art;
- (F) The amount of direction provided by the inventor;
- (G) The existence of working examples; and
- (H) The quantity of experimentation needed to make or use the invention based on the content of the disclosure.

In the instant case applicants do not provide any definition or description of the term oligoelements and what compounds or components are encompassed by the term. Thus, applicants have not provided any guidance in the specification such that one of an ordinary skill in the art could practice the invention. Further, the instant examples do not recite or state the term "oligoelements". Accordingly, one of an ordinary skill in the art would not know what applicants are referring to by the claimed term, is it a protein or a peptide or an inorganic compound etc. Instant invention is directed to a composition for the restoration of potassium and sodium i.e., reads on an electrolyte composition. Electrolyte compositions are known to contain salts such as sodium chloride, potassium chloride, magnesium phosphate, calcium source and other energy sources such as sugar, vitamins etc. The prior art teaches oligoelements such as copper, chromium, iron and zinc in nutritional compositions in general, and incorporate these elements for the treatment of conditions associated with deficiencies of these elements (see US 5,334,408, col. 10, lines 33-48). However, instant claims are directed to rehydrating drink, in particular for heat stress and applicants have not described whether incorporating any oligoelements would have any advantage in restoring the electrolytes such as potassium, sodium. Accordingly, without any guidance or direction as to what specific oligoelements are to be

included in the instant composition to be effective for the claimed effect, a skilled artisan would have to perform undue experimentation to determine which one of the oligoelements and in what amounts are required for practicing the instant invention.

2. Claim 6 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for vitamin C and vitamin E, does not reasonably provide enablement for dermoprotective vitamins. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Instant claims recite dermoprotective vitamins in the composition for relieving heat stress. However, the specification describes only ascorbic acid, tocopherol and beta-carotene as vitamins that are included in the composition. The specification nowhere provides any description of dermoprotective vitamins or what vitamins are encompassed by the term. It is generally known that vitamin C, vitamin E and beta-carotene are used for both topical as well as oral administration for providing skin care. However, without any guidance in the specification regarding other vitamins that possess a dermoprotective effect one of an ordinary skill in the art would not be able to determine what other vitamins, other than vitamin C, vitamin E and beta-carotene, could be incorporated in the instant composition so as to provide maximum protection from heat stress.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1, 3-7 and 12 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Instant claims 1, 3-5 and 7 recite the amounts of different components such as sodium, potassium etc., as “parts in weight”, which is indefinite because, without reciting the total weight of the composition, the expression “parts in weight” is vague and unclear and does not clearly state as to how much of each components is required. Further, the instant expression “parts in weight” does not remain constant and when the total weight of the composition is changed. For instance, 100 parts of a compound in 100 ml of the composition gives a different percentage of the compound as opposed to 100 parts in 1000 ml. The general expression would be parts per 100 or parts per 1000 or parts per million or parts per billion. For the purposes of prosecution, examiner interprets the amounts of components per liter amounts as given on page 16 of the instant specification. Claim 1 also recites the phrase “for organoleptic purposes only”, which is indefinite because the term has not been defined in the specification. While the dictionary meaning of organoleptic relates to qualities of taste, smell, color or feel, it is unclear to the examiner as which one of these are being contemplated upon by the instant term. Examiner interprets as “for taste only”. However, a clarification and appropriate correction is requested.

Further, claim 7 recites “oligoelements, dermoprotective vitamins and antioxidants selected in the group comprising (g) from 2.5 to 250 parts rutin, (h) from 0.04 to 0.3 parts of biotin, (i) from 15 to 120 parts of vitamin C, (j) from 4 to 30 parts of beta-carotene, and (k) from 2.5 to 20 parts of vitamin E”. The claim is indefinite because it is not clear if the claim requires

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one of the three i.e., oligoelements, dermoprotective vitamins or antioxidants or all three.

Further, the claim does not list any oligoelements in the markush group and only lists vitamins and an antioxidant, rutin. If applicants intend to claim any one of oligoelements, dermoprotective vitamins and antioxidants, then it is suggested that claim be amended so. For the purpose of examination, examiner interprets the claim as requiring all three (oligoelements, dermoprotective vitamins and antioxidants) because the claim is dependent from claim 6, which requires the presence of all three. A clarification and appropriate correction is requested.

Claim 6 is indefinite because the terms “oligoelements and dermoprotective vitamins” are vague and unclear. Applicants do not provide any definition of the above terms and accordingly, it is unclear to the examiner as to what these terms encompass. Does the term “oligoelements” encompass organic or inorganic compounds, what is the nature of the compounds? How are the instant “dermoprotective vitamins” different from the regular vitamins such as vitamin C, vitamin E, vitamin B. Is it a new class of vitamins? A clarification and appropriate correction is requested.

Claim 12 is indefinite because of the phrase “where in for each liter of beverage each part by weight of composition ion corresponds to 1 mg”. It is unclear as to what applicants intend to claim. Examiner interprets as the “parts by weight” recited in claim 1 stands for “mg” and accordingly the composition when solubilized contains sodium, potassium and magnesium in amounts such as those recited on page 16, lines 10-12. A clarification and appropriate correction is requested.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 5, 6, 8-10 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by US 5,114,723 to Stray-Gundersen (hereafter US ‘723).

Instant claims are directed to a composition comprising sodium ion, magnesium ion, potassium ion, carbohydrates, zinc, calcium, vitamin C, vitamin E, rutin and biotin, which is useful for heat stress, including selective restoration of the potassium and magnesium ion.

US ‘723 discloses compositions comprising essential electrolytes, water, carbohydrates, antioxidants and other ingredients, as a replenishing drink to a person stressed by exercise, heat or illness (cols. 4-5, summary of the invention). In particular, US ‘723 discloses various amounts of sodium chloride, potassium salts such as potassium phosphate, calcium, vitamins A, B, C, E etc., in cols. 8-9. The compositions of ‘723 are exemplified in examples I to IV in cols. 12-14. Vitamins C and E of US ‘723 meet the requirement of antioxidants of claim 6. With respect to oligoelements, US ‘723 teaches iron (example 1), which reads on the instant term.

Instant claims express the amounts of various components in “parts in weight”. Examiner has explained above that the amounts are interpreted as mg/liter, based on the description in the specification. US ‘573 teaches the amounts of various components of the compositions as meq./l (milliequivalents per liter). Milliequivalents of a compound or element is calculated as one-thousandth of the equivalent weight of a compound or an element. Accordingly, converting the

amounts of various components in the composition (example 1, in col. 12) of US '723, from milliequivalent per liter to instant mg/liter, US '723 teaches sodium-230 mg/l, potassium-390 mg/l and calcium-120 mg/l. Thus, the amounts of sodium, potassium and calcium taught by US '723 are within the range of the claimed amounts. US '723 also teaches 100 mg/l of Vitamin C, which falls within the claimed range of 15 to 120 mg/liter (instant specification page 16). With respect to the amount of magnesium ions, US '723 discloses between 1 to 5 meq./liter (col. 9, lines 4-13) i.e., 24 mg to 120 mg/l. US '723 teaches using carbohydrate in the range of 1 to 2% for dextrose, by weight based on the total weight of the compositions (col. 9, lines 66-68 and col. 10, lines 1-11), which is within the claimed. US '723 further teaches preparing dry mixtures of the compositions (col. 12, lines 38-41). Accordingly, US '723 anticipates the instant claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 11 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,114,723 to Stray-Gundersen (hereafter US '723).

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any

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evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Instant claim 11 requires that the composition be in a frozen state. Claim 13 recites that the carbohydrate contributes to no more than 120 kcal per liter of beverage.

US '723 does not specifically teach no more than 120 kcal per liter of beverage (as claimed). However, the reference teaches carbohydrate amounts in the same range as claimed, and also suggests that large amounts of glucose in such drinks would trigger a sudden and transient insulin response causing further imbalance of carbohydrate metabolism. Therefore, it would have been obvious for a skilled artisan at the time of the instant invention to optimize the amounts of carbohydrates in the replenishing beverage of US'723, with an expectation to provide an optimum amount carbohydrate source sufficient to provide sustained glucose level and in turn, enough calories in a person stressed due to heat and exercise, without depleting the carbohydrate levels due to insulin release. US '723 does not specifically mention the composition in a frozen state. However, absent any criticality, storing a beverage composition in different forms and at different temperatures, without losing the activity of the components such as carbohydrates and vitamins is deemed to be within the scope of a skilled artisan.

5. Claims 3, 4 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,114,723 to Stray-Gundersen (hereafter US '723) as applied to claims 1, 2, 5, 6 and 8-13, further in view of 5,292,538 to Paul et al (hereafter '538).

US '723, discusses above, does not teach zinc and manganese of the instant claims in their composition. US '723 also fails to teach biotin, rutin and beta-carotene of instant claim 7. However, with respect to the markush expression of the instant claim (see above 35 USC 112, rejection), examiner interprets the claim as comprising oligoelements, vitamins, antioxidants, wherein the vitamins and antioxidants are selected from the group consisting of rutin, biotin, vitamin C, beta-carotene and vitamin E.

US '538 teaches a sustained energy composition to combat the consequences of strenuous physical exercise, trauma, malnutrition etc., comprising a blend of carbohydrates, minerals, electrolytes, vitamins such as A, B complex, C, D and E, biotin, antioxidants etc. US '538 suggests adding bioavailable forms of minerals such as magnesium, zinc, manganese, boron etc., as amino acid chelates to facilitate sustained endurance and anabolism (col. 5, lines 5 through col. 6, lines 18). Further, the amounts of zinc and manganese taught by US '538 are within the range of the amounts claimed in the instant (see table in col. 10 through col. 11). Therefore, it would have been obvious for a skilled artisan at the time of the instant invention to add manganese, zinc, biotin and beta-carotene of US '538 in the nutritional composition of US '723, with an expectation to provide a complete nutrition with sustained energy and anabolism to a person stressed with physical exercise. The amounts of beta-carotene and biotin are mentioned in International Units and milligrams respectively, in the composition of US '538 (see example in col. 11). These amounts are different from that claimed in the instant invention. However, absent any criticality, optimizing the amounts of beta-carotene and biotin in the composition of US '732 would have been within obvious for one of ordinary skill in the art at the time of the instant invention because US '538 suggests that biotin and beta-carotene possess antioxidant activity

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required to protect against the generation of free radicals and oxidative damage (col. 7, lines 43-68).

6. Claims 14-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stray-Gundersen (US '723) and 5,292,538 to Paul et al (US '538) as applied to claims 1-13 above, and further in view of EP 387 042 (EP '042).

US '723 and US '538 teach rehydrating compositions useful for people under heat stress or strenuous physical exercise (see above). Both US '538 and US '732 teach the addition of antioxidants in their compositions to reduce the damage caused by free radicals (col. 7, lines 12-15 of '723 and col. 7, lines 61-68 of '538). However, neither of them teaches rutin in their compositions.

EP '042 teaches rutin as an antioxidant, nutritive element and a stabilizer in various drinks, foods, beverages etc., and also as a preventive and remedy for diseases (see col. 1). EP '042 also teaches that rutin, which is also called as vitamin P, takes part in the activities of Vitamin C, causes immunopotentiation via the increase of leukocytes and thus maintains and promotes health (col. 1 and col. 10). Further, EP '042 teaches incorporating various amounts of rutin (0.01 to 5.0% w/w) (examples in col. 21-26 and col. 27, lines 1-9). In particular, EP '042 teaches rutin in the amounts of 0.01 to 2.0% w/w in foods and beverages, which is within the claimed range of 0.025 to 0.25 g/liter. Therefore, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention to incorporate an appropriate amount of rutin (0.01 to 2.0% w/w) of EP '042, as an antioxidant, in the beverage composition of US '723, with an expectation to reduce the damage due to oxygen free radicals, to stabilize the

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composition and also to maintain and promote the health of an individual who is stressed due to heat and physical exercise.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S. Channavajjala whose telephone number is 703-308-2438. The examiner can normally be reached on 7.30 AM -4.00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-7924 for regular communications and 703-308-7924 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.


Lakshmi S Channavajjala
Examiner
Art Unit 1615
May 18, 2002